



FEE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D446472; **FILE SYMBOL No.:** 88051-A; **PRODUCT NAME:** Zeronil Plus Spot-On Solution for Dogs; **DECISION No.:** 536613; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Chanelle Pharmaceuticals Manufacturing Ltd.

DATE OUT: September 19, 2018

SUBJECT: End Use Product Chemistry Review
Product Name: Zeronil Plus Spot-On Solution for Dogs

FROM: Shyam Mathur, Ph. D
Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

Prashant
10/11/2018

TO: Julie Breeden-Alemi, I-V Branch 1 / RD (7505P)

INTRODUCTION:

The registrant has applied for the registration of the new end use product Zeronil Plus Spot-On Solution for Dogs. The registrant has submitted a CSF for basic formulation and an alternate formulation CSF #1 (both dated March 19, 2018) and the supporting the product chemistry data with MRID Nos. 50442701, 50442702 and 50430002. On the advice of the Agency, the registrant submitted the revised basic CSF and alternate CSF #1 both dated September 17, 2018 which reflect the correct registration numbers & purities of the active ingredients used in the formulation of the product. CITAB has been asked to determine the acceptability of the proposed revised CSF's and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s):

Active ingredient	Reg. No.	NC of AI in product	PC code
Fipronil Technical			129121
(s)-Methoprene			105402

****Product ingredient source information may be entitled to confidential treatment****

2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No.:

DP BARCODE No.: D446472; **FILE SYMBOL No.:** 88051-A; **PRODUCT NAME:** Zeronil Plus Spot-On Solution for Dogs; **DECISION No.:** 536613; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Chanelle Pharmaceuticals Manufacturing Ltd.

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No
4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 03-19-2018; Re-submitted - Dated: 9-17-2018

☒ Alternate CSF #1 – Dated: 03-19-2018; Alternate CSF – Dated: 9-17-2018; Re-submitted CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Soluble arsenic:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Isomeric ratios:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Acid Equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA: acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA
Methanol at > 4%:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA
Sodium nitrate/Sodium nitrite	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: D446472; **FILE SYMBOL No.:** 88051-A; **PRODUCT NAME:** Zeronil Plus Spot-On Solution for Dogs; **DECISION No.:** 536613; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Chanelle Pharmaceuticals Manufacturing Ltd.

7. Group A: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50442701
830.1600	Description of materials used to produce the product		X		A	50442701
830.1650	Description of formulation process		X		A	50442701
830.1670	Discussion on the formation of impurities		X		A	50442701
830.1700	Preliminary analysis		NA			
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Revised Basic CSF dated 9-17-2018
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method			X	A	50430002 HPLC-UV (210 ¹ , 240 ² nm) method with external standard calibration. Method validation provided.

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

¹ Fipronil and ²S-Methoprene

DP BARCODE No.: D446472; **FILE SYMBOL No.:** 88051-A; **PRODUCT NAME:** Zeronil Plus Spot-On Solution for Dogs; **DECISION No.:** 536613; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Chanelle Pharmaceuticals Manufacturing Ltd.

8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Pale amber liquid with faint characteristic odor	A	50442702
830.6315	Flammability	39°C (102.2°F)	A	50442702
830.6316	Explodability	TS is not potentially explosive and does not contain explosive properties	NA	50442702
830.7000	pH	TS is not dispersed in water and therefore, pH value can-not be measured	NA	50442702
830.7300	Density (units)	1.02 g/ml (8.50 lbs/gal) at 20°C	A	50442702
830.7100	Viscosity	9.95 cP s @ 20°C	A	50442702
830.6317	Storage stability	Study in progress	I	50442702
830.6320	Corrosion characteristics	Study in progress	I	50442702
830.6314	Oxidation/reduction	Not expected to be oxidized nor reduced based on the chemical structures of the constituents	NA	50442702

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable; I = In progress

DP BARCODE No.: D446472; **FILE SYMBOL No.:** 88051-A; **PRODUCT NAME:** Zeronil Plus Spot-On Solution for Dogs; **DECISION No.:** 536613; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Chanelle Pharmaceuticals Manufacturing Ltd.

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No.) from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons:
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement of formula

1. Revised Basic CSF (dated: 09-17-2018)
 - ☒ Acceptable
 - ☐ Not Acceptable:
 - ☐ Not Applicable
2. Revised Alternate CSF #1 (dated: 09-17-2018)
 - ☒ Acceptable
 - ☐ Not Acceptable:
 - ☐ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Acceptable with the exception of the guideline:
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited

D. Group B Product chemistry data

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics). Registrant indicated that these two studies are in progress and the results will be submitted on completion.
- ☐ Not required
- ☐ Data cited
- ☒ Waiver requests – ☐ Acceptable; ☐ Not Acceptable, ☒ Not applicable

Product Label/Draft Label: Recommendations – Yes ☒; No ☐

Note to PM: Since the Flash point of the product was found to be 102.2°F, the registrant is recommended to add the following warning on the product label under Physical-Chemical Hazardous in compliance with 40CFR§156.78: "Combustible. Do not use near or expose to open flame"

